CLAIMS

1. Addition salt of azithromycin and citric acid, in which the molar ratio between the azithromycin and the citric acid is such as to provide a pH between 4.0 and 8.0 in a 10% aqueous solution.

2. Addition salt of azithromycin according to Claim 1, characterised in that it is azithromycin hydrogen citrate.

3. Addition salt of azithromycin according to Claim 1, characterised in that it is azithromycin citrate.

4. Addition salt of azithromycin according to Claim 1, characterised in that it includes up to 8% water.

5. Addition salt of azitromycin according to Claim 4, characterised in that it further includes up to 6% by weight of water.

6. Addition salt of azithromycin according to Claim 1, which further contains up to 3% of residual matter.

7. Addition salt of azithromycin according to Claims 1 and 2, characterised in that the salt has a molar ratio of azithromycin and citric acid such that it provides a pH between 4.0 and 6.0 in a 10% aqueous solution.

8. Addition salt of azithromycin according to Claims 1 and 3, characterised in that the salt has a molar ratio of azithromycin and citric acid such as to provide a pH between 6.0 and 8.0 in a 10% aqueous solution.

9. Addition salt of azithromycin according to Claim 2 and 4, characterised in that with the molar ratio of azithromycin and citric acid being 1:1 a pH of 5 is provided in a 10% aqueous solution.

10. Addition salt of azithromycin according to Claims 3 and 5, characterised in that the molar ratio of azithromycin and citric acid is 3:2.

11. Addition salt of azithromycin according to Claim 3, characterised in that it is in an amorphous state.

12. Process for preparing an addition salt of azithromycin and citric acid according to Claim 1, characterised in that it comprises:

a) dissolving azithromycin in a solvent or mixture of solvents;

b) adding citric acid; and

c) isolating the product obtained.

13. Process according to Claim 12, characterised in that azithromycin is dissolved in monohydrated form in step (a).

14. Process according to Claim 12, characterised in that azithromycin is dissolved in dihydrated form in step (a).

15. Process according to Claim 12 characterised in that the solvent is selected from: water; the linear or branched C_1-C_6 aliphatic alcohols, such as methanol, ethanol, n-propanol, isopropanol, n-butanol; cyclic aliphatic alcohols, such as cyclohexanol; diols, such as ethylene glycol, 1,2-propylene glycol, 1,3-propanodiol, 1,4-butanodiol; linear or branched C_1-C_6 aliphatic

ketones, such as acetone, methyl ethyl ketone, methyl isobutyl ketone; cyclic aliphatic ketones, such as cyclohexanone; short-chain aliphatic esters, such as ethyl acetate; short-chain aliphatic ethers, such as ethylic ether, isopropylic ether, etc.; cyclic aliphatic ethers, such as tetrahydrofuran and dioxane, or mixtures thereof.

16. Process according to Claim 15, characterised in that the azithromycin monohydrate or dihydrate is dissolved; the solvent is selected from water, alcohols, ketones, esters or ethers, or mixtures thereof, preferably water, ethanol, acetone, methyl acetate or tetrahydrofuran, or mixtures thereof.

17. Process according to any of Claims 12 to 16, for the preparation of azithromycin hydrogen citrate, characterised in that an amount of citric acid is added in step (b) such that the molar ratio between the azithromycin and the citric acid is close to the stoichiometric.

18. Process according to any of Claims 12 to 17, for the preparation of azithromycin hydrogen citrate, characterised in that in step (c) the salt is isolated by crystallisation.

19. Process according to Claim 18, characterised in that step c) comprises:

c-i) crystallising at a crystallisation temperature between 25°C and the solvent's reflux temperature; and

c-ii) cooling the mixture at a temperature between 0°C and 25°C, before separating the cystals.

20. Process according to any of Claims 12 to 17, for the preparation of azithromycin citrate, characterised in

that an amount of citric acid is added in step b) such that the molar ratio between the azithromycin and the citric acid is 3:2.

21. Process according to any of Claims 12 to 17 and 20, characterised in that for the preparation of azithromycin citrate, the salt is isolated by removing the solvent in step c).

22. Process for preparing solutions of an addition salt of azithromycin and citric acid according to Claim 1, in water or water-alcohol mixtures of up to 65%, which consists on: dissolving the azithromycin citrate in water and filtering the solution obtained.

23. Process for preparing solutions of at least one addition salt of azithromycin and citric acid, according to Claim 1, in water or water-alcohol mixtures of up to 65%, which consists on:

a) dissolving both components, azithromycin and citric acid, by stirring at ambient temperature; and

b) filtering the solution obtained.

24. Azithromycin salt according to any of Claims 1 to 11 for use as an antibacterial agent.

25. Azithromycin salt according to any of Claims 1 to 11 for use as an antiprotozoan agent.

26. Use of an azithromycin salt according to any of Claims 1 to 11 for the manufacture of a medicament for the treatment of an infection caused by bacteria or protozoans.

27. Use of an azithromycin salt according to any of Claims 1 to 11 for the manufacture of a medicament for the prevention of an infection caused by bacteria or protozoans.